Application No.: 10/658,219 Docket No.: 559662000102

CLAIMS AMENDMENT

- 1-19. (canceled)
- 20. (new): A vial containing a dry native Factor VIII composition comprising a Factor VIII-stabilizing amount of trehalose and no albumin, the composition being
 - (a) stable without refrigeration, and
- (b) suitable for reconstitution with water or with an aqueous solution for administration to a hemophilic patient by injection.
- 21. (new): The composition of claim 20, containing 0.15 to 2.5 mg trehalose per unit of Factor VIII.
 - 22. (new): The composition of claim 20, wherein said native Factor VIII is recombinant.
- 23. (new): The composition of claim 20, containing 1.0 to 1.5 mg Ca²⁺ per unit of Factor VIII.
- 24. (new): The composition of claim 20, wherein the composition comprises salt and the molar ratio of trehalose to the salt is above 1:1.
- 25. (new): The composition of claim 24, containing more than 2.5 moles trehalose per mole of salt.
- 26. (new): The composition of claim 25, containing more than 10 moles trehalose per mole of salt.
- 27. (new): A process of preparing a dry native Factor VIII composition comprising a Factor VIII-stabilizing amount of trehalose and no albumin, the composition being
 - (a) stable without refrigeration, and

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(b) suitable for reconstitution with water or with an aqueous solution for administration to a hemophilic patient,

the process comprising drying a solution of native Factor VIII and trehalose in the absence of albumin.

- 28. (new): The process of claim 27, wherein the drying is done at a temperature of no greater than 10°C.
 - 29. (new): The process of claim 28, wherein the drying is freeze-drying.
- 30. (new): The process of claim 29, wherein an aliquot of the solution is placed in a vial and is freeze-dried.
- 31. (new): The method for preparing a Factor VIII therapeutic composition for administration to a patient wherein the method comprises reconstituting the composition of claim 20 to obtain a solution that is suitable for injection.
 - 32. (new): The method of claim 31, wherein the composition is reconstituted with water.
- 33. (new): The method of claim 31, wherein the composition is reconstituted with saline.

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